UNITED STATE DISTRICT COURT
FOR THE DISTRICT OF COLORADO

DAVID R. DUNN, Plaintiff, vs. PFIZER, INC., PHARMACIA CORPORATION, MONSANTO COMPANY, AND G.D. SEARLE & COMPANY, Defendants.	)	CIVIL ACTION NO.:_____

PLAINTIFF'S ORIGINAL COMPLAINT

PLAINTIFF'S DEMAND FOR TRIAL BY JURY

COMES NOW the Plaintiff, David R. Dunn, and for cause of action would respectfully show to the Court and the Jury the following:

I.

1. This is a civil action brought on behalf of Plaintiff regarding a heart attack that occurred as a result of the ingestion of CELEBREX® by Plaintiff at age 56. Plaintiff David R. Dunn ingested CELEBREX® daily and suffered heart attack while on Celebrex®. Plaintiff's heart attack occurred on or about July 24, 2002.

II.

PARTIES

2. Plaintiff is an individual citizen of the State of Colorado and a resident of Douglas County, Colorado.

3. Defendants Pfizer Inc. ("Pfizer"), Pharmacia Corporation ("Pharmacia"), Monsanto

Co. ("Monsanto") and G.D. Searle & Co. ("Searle") tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold and distributed, or otherwise placed in the stream of interstate commerce, Celebrex®, which was ingested by the Plaintiff, David R. Dunn. Defendants have committed a tort within the State of Colorado and may be served with process of this Court in accordance with Rule 4 of the Federal Rules of Civil Procedure through its registered agent for service of process.

4. Defendant Pharmacia is a Delaware corporation, authorized to do and doing business in the State of Colorado, with its principal place of business in New Jersey. On information and belief, said entity does business in the state of Colorado, and at all times relevant herein, it developed, manufactured, marketed, distributed, and sold Celebrex® in interstate commerce.

5. Defendant Monsanto, a subsidiary of Pharmacia, authorized to do and doing business in the State of Colorado, is a Delaware corporation with its principal place of business in Missouri. On information and belief, said entity does business in the state of Colorado and at all times relevant herein, it developed, manufactured, marketed, and sold Celebrex® in interstate commerce.

6. Defendant Pfizer is a Delaware corporation, authorized to do and doing business in the State of Colorado, with its principal place of business in New York. In 2003, Pfizer acquired Pharmacia for nearly $60 billion because of Celebrex®. During the relevant time period, Pfizer has been engaged in the business of marketing and selling Celebrex® nationwide and in Colorado.

7. Defendant Searle is a Delaware corporation, authorized to do and doing business in the State of Colorado, with its principal place of business in Illinois. At all relevant times, Searle

has been engaged in the business of marketing and selling Celebrex® nationwide and in Colorado.

III.

JURISDICTION AND VENUE

8. This Honorable Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332, as the amount in controversy exceeds $75,000 exclusive of interest and costs and because this action is brought by an individual who is a citizen of a state other than the Defendant.

9. Venue is proper in this district pursuant to 28 U.S.C. § 1391 in that a substantial part of the events or omissions giving rise to the claims asserted herein occurred in this District, and Defendants are subject to personal jurisdiction in this District. Plaintiff purchased, consumed and was injured by the products that form the basis of this lawsuit in the State of Colorado. Defendants do substantial business in the State of Colorado and within this Federal District, advertise in this district, received substantial compensation and profits from sales of CELEBREX® in this district, and made material omissions and misrepresentations and breaches of warranties in this district.

10. All conditions precedent have been performed or have occurred.

IV.

FACTUAL ALLEGATIONS

A. General Allegations

11. Defendants are in the business of designing, manufacturing, marketing, developing, testing, labeling, promoting, distributing, warranting and selling their product, CELEBREX®. Defendants at all times relevant hereto, designed, developed, manufactured, promoted, marketed, distributed, tested, warranted and sold CELEBREX® in the State of Colorado.

12. Plaintiff David R. Dunn, at age 56, ingested CELEBREX® as prescribed and as a result thereof, suffered a heart attack on or about July 24, 2002.

13. At all times relevant herein, Plaintiff David R. Dunn was unaware of the serious side effects and dangerous properties of the drug as set forth herein.

14. The product in question was designed, formulated, patented, marketed, sold, tested, warranted, and ultimately distributed by the Defendants as CELEBREX®.

B. Development of Celebrex®

15. Celebrex® is one of the new entries in a class of pain medications called nonsteroidal anti-inflammatory drugs ("NSAIDs"). Aspirin and ibuprofen are examples of well known NSAIDs.

16. NSAIDs reduce pain by blocking the body's production of pain transmission enzymes called cyclooxygenase or "COX." There are two forms of COX enzymes, COX-1and COX-2.

17. In addition to transmitting pain sensations, COX-1 is involved in maintaining and repairing gastrointestinal tissue.

18. In addition to transmitting pain sensations, COX-2 is involved in the production of prostacyclin, a substance responsible for preventing the formation of blood clots.

19. It is generally accepted in the medical community that blocking the COX-1 enzyme hampers the body's ability to repair gastric tissue and causes harmful gastrointestinal side-effects, including stomach ulceration and bleeding.

20. It is generally accepted in the medical community that blocking the COX-2 enzyme encourages the formation of blood clots and causes various clot-related cardiovascular events, including: heart attack, stroke, unstable angina, cardiac clotting and hypertension.

21. Traditional NSAIDs, like aspirin, reduce pain sensations by inhibiting both COX-1 and COX-2 enzymes simultaneously. As would be expected, traditional NSAIDs can cause ulcers in the stomach and intestines. However, because of a complex chemical balance in the human body, traditional NSAIDs do not cause blood clots, but actually reduce the risk of clots and help to protect heart function.

22. For decades, in the absence of other treatment options, consumers seeking pain relief were forced to accept and live with the gastrointestinal risks of traditional NSAIDs.

23. Defendants set out to remedy this problem by developing "selective" inhibitors that would block only COX-2 production, thus (supposedly) allowing the proper maintenance of gastric tissue while still reducing pain sensations. In making this decision, Defendants either intentionally ignored or recklessly disregarded then current medical knowledge that selective COX-2 inhibition lowers prostacyclin levels, causes blood clots and gives rise to various clot-related cardiovascular events, including: heart attack, stroke, unstable angina, cardiac clotting and hypertension.

24. Defendants Pharmacia and Monsanto completed Phase I, II and III trials for their selective COX-2 inhibitor, Celebrex®, by 1998. During these trials, they learned that selectively inhibiting the COX-2 enzyme lowers prostacyclin levels, causes blood clots and gives rise to various clot-related cardiovascular events, including: heart attack, stroke, unstable angina, cardiac clotting and hypertension.

C. The CLASS Study

25. Thus, Defendants knew by 1998 that selective COX-2 inhibitors posed serious cardiovascular risks for anyone who took them, and presented a specific additional threat to anyone with existing heart disease or cardiovascular risk factors.

26. Despite knowing that Celebrex® posed serious cardiovascular risks for anyone who took them, Defendants made a business decision to push Celebrex® to market on claimed improvements in gastrointestinal safety while downplaying their cardiovascular dangers.

27. In order to justify this position, Defendants funded a significant clinical trial to demonstrate that Celebrex® had greater gastrointestinal safety than traditional NSAIDs: the Celecoxib Long-Term Arthritis Safety Study ("CLASS").

28. The CLASS trial, paid for by Pfizer, Pharmacia, Monsanto and Searle, was a long-term, double-blind study of gastrointestinal toxicity in 8,059 patients taking Celebrex®, ibuprofen or diclofenac to treat arthritis. Patients with heart problems were allowed to participate in the CLASS trial, and were permitted to take low doses of aspirin to reduce the risk that they would suffer an adverse cardiovascular event during the study.

29. Despite the fact that the CLASS studies secretly acknowledged the likelihood of cardiovascular events (as shown by the attention paid to whether participants would be permitted to take aspirin, a known cardio-protector, and the fact that the studies were both set up to record cardiovascular event data), Defendants intentionally diverted attention from cardiovascular risks of Celebrex® by providing the bare minimum of information on this issue: the CLASS trial did not publish any cardiovascular event data.

30. When the CLASS study was completed, the results were reported to the U.S. Food and Drug Administration's Arthritis Drugs Advisory Committee ("the Committee") as part of a request to exempt Celebrex® from including a gastrointestinal safety warning in its package insert.

31. After reviewing the CLASS results, the Committee concluded that patients taking Celebrex® had not experienced fewer gastrointestinal complications than those taking traditional

NSAIDs. Without any proof of enhanced safety, the Committee recommended that the Celebrex® package insert contain the same gastrointestinal warnings as traditional NSAIDs, and advised further studies to assess the risk of COX-2 inhibitors when taken with aspirin.

32. Since the CLASS study did not report any cardiovascular event data and the Celebrex® Defendants were not seeking an exemption from any cardiovascular warning requirement (because traditional NSAIDs do not cause cardiovascular problems), the Committee did not consider the cardiovascular safety of Celebrex®.

33. Defendants' clinical studies did not have their intended effect, as the drug was not permitted to claim increased gastrointestinal safety over traditional NSAIDs.

34. Defendants initiated extensive pre-release marketing campaigns to convey the uniform message that Celebrex® provided effective pain relief without the gastrointestinal side-effects of traditional NSAIDs. Defendants intentionally omitted any mention of cardiovascular risks from their marketing and advertising statements to benefit from the inference that Celebrex®, as a pain reliever in the NSAID family, had a cardio-protective effect.

35. Defendants also pushed ahead with their efforts to win approval from the U.S. Food and Drug Administration ("FDA") to sell Celebrex® in the United States.

36. Without having performed any significant tests on cardiovascular safety, the Celebrex® Defendants filed a new drug approval application with the FDA in August 1998. After an expedited review that addressed the CLASS gastrointestinal safety results but did not touch on any cardiovascular safety issues, the FDA approved Celebrex® for the relief of osteoarthritis and adult rheumatoid arthritis in December 1998. Celebrex® was released for sale in the United States in February 1999.

37. By this time, Defendants' intensive marketing campaigns were already showing

positive results. Sales projections for Celebrex® based on early orders and inquiries surpassed $2 billion per year.

38. The results of the CLASS study were published in the September 13, 2000, issue of JAMA. CLASS is what's known as a Phase 4 post approval study, which was required by the FDA. Before any drug is approved, manufacturers have to submit data to the FDA that demonstrate the drug's safety and effectiveness.

39. CLASS, which included over 8000 people with rheumatoid and osteoarthritis, compared the risk of gastrointestinal problems in people taking Celebrex® with the risk in those taking ibuprofen (Motrin, Advil) and diclofenac (Voltaren). ***The article in JAMA concluded that Celebrex®, "when used for 6 months ... is associated with a lower incidence of clinical upper GI events than comparator NSAIDs (ibuprofen and diclofenac)."*** The accompanying editorial supported this conclusion: "The results of this important study ... provide ***promising data*** to suggest that [Celebrex® is] ... ***effective in reducing***, but not eliminating, the risk of symptomatic [minor] ulcers and [major] ulcer complications in the enormous number of individuals who might benefit from these drugs..."

40. There was, however, one very large problem. The manufacturer's original research plan, as submitted to the FDA, had defined the duration of the CLASS study that compared Celebrex® with ibuprofen as 12 months, and that of the study comparing Celebrex® with diclofenac as 16 months. And, indeed, the combined study had run for a full 12 months. ***The authors, however, submitted only the first 6 months for the article in JAMA.*** Left unreported (and unmentioned) in the JAMA article were the data from the *second* 6 months of the study, during which time, as shown in the data on the FDA's website, ***six of the seven serious gastrointestinal complications that occurred were in patients taking Celebrex®.***

41. Pharmacia, the manufacturer of Celebrex®, presented a statistical argument to the FDA justifying its omission of the data from the second half of its study. The company claimed that since a higher percentage of people taking diclofenac dropped out of the study because of minor symptoms like heartburn, the data from the second half of the study were invalid because of what is called "informed censoring." The manufacturer argued that these dropouts would have gone on to develop serious gastrointestinal complications, and their dropping out of the study artificially minimized the risk of serious complications from taking diclofenac. The FDA flatly rejected this argument. It countered that there was no proof that the people with heartburn would have developed more serious gastrointestinal problems. Further, if minor symptoms caused people in the study to stop taking diclofenac, people in the real world would similarly stop taking the drug if it caused heartburn and would similarly protect themselves from going on to develop serious gastrointestinal complications.

42. The FDA's opinion of the manufacturer's decision to publish only half of the data from its study was clear: "the sponsor's presentations of 6-month data ... are not statistically valid or supportable." The FDA's gastroenterology reviewer concluded that the first 6 months of data – which had been presented in the JAMA article as if they were a report of the entire study – were not worthy of separate consideration: "Based on the lack of adequate rationale, these post-hoc analyses will not be further discussed or presented in this review." Looking at the data from the entire year of the study, the FDA's gastroenterology reviewer concluded that "the sponsor has failed to demonstrate a statistically significant lower rate" of serious GI complications in the people who took Celebrex® compared with the people who took the other NSAIDs. When the reviewer looked at only the second six months of data (*i.e.*, the data that had not been published in the JAMA article), she concluded that the risk of serious GI complications appeared to be

higher in the people who took Celebrex® "compared to both ibuprofen and diclofenac." This was hardly an endorsement for a drug whose only advantage (besides the convenience of a once daily dosing) was that it caused fewer serious GI problems.

43. The disparity between the CLASS article published in JAMA and the information in the FDA's files by no means stopped there. The primary question that the CLASS study had been designed to answer had been changed, producing results that were far more favorable to the manufacturer. The original research design submitted to the FDA by the manufacturer of Celebrex® had stated: "The primary objective of this study is to compare the incidence of ***clinically significant*** [major] upper gastrointestinal events … in patients taking Celebrex® to patients taking NSAIDs." The term "***clinically significant***" refers to complications that would generally require hospitalization: active bleeding, perforation of the stomach or duodenum requiring surgery, or obstruction of the outlet of the stomach. The research plan specifically called for the less serious gastrointestinal side effects to "be categorized and analyzed separately." Indeed the FDA's gastroenterology reviewer specifically commented that the plan to identify the "truly significant" serious gastrointestinal complications alone was a "major strength of the current study."

44. But when the results of the study were published in JAMA, the incidences of major and minor gastrointestinal complications were combined. Why the change? The results of the study as originally designed failed to show that the people who took Celebrex® developed significantly fewer major gastrointestinal complications than the people who took ibuprofen or diclofenac, even for just the first six months. Only by combining the minor GI symptoms with the more serious gastrointestinal complications could the article conclude that Celebrex® caused a statistically significant decrease in gastrointestinal complications compared with the other

NSAIDs. As noted above, when the FDA looked at the results of the CLASS study in terms of the research question that had *originally* been posed, Celebrex® was not significantly safer than the other NSAIDs.

45. Finally, the most important measure of safety is the overall frequency of serious side effects – including but not limited to gastrointestinal side effects. For the full 12 months of the study, the people in the CLASS study who took Celebrex® experienced 11 percent more serious complications (in all body systems combined) than the people who took the older and less expensive anti-inflammatory drugs. This difference did not reach statistical significance but certainly is significant in countering Pharmacia's claim that Celebrex® is better than older NSAIDs because it's safer.

46. These findings contributed to the FDA's decision to send one of its rare Warning Letters to the CEO of Pharmacia in February 2001. The letter cites repeated unsubstantiated marketing claims that Celebrex® is the preferred NSAID for people taking a blood thinner and that it is safe and effective for the treatment of acute pain – a use for which it is not approved – and points out that Pharmacia's marketing material fails to warn of the possibility of serious GI complications caused by the drug. The Warning Letter concludes by saying:

> Your promotional activities described above raise significant health and safety concerns in that they minimize crucial risk information and promote Celebrex® for unapproved new uses. In two previous untitled letters dated October 6, 1999, and April 6, 2000, we objected to your dissemination of promotional materials for Celebrex® that … contained unsubstantiated comparative claims, and lacked fair balance. Based upon your written assurances that this violative promotion of Celebrex® had been stopped, we considered these matters closed. Despite our prior written notification, and notwithstanding your assurances, Pharmacia has continued to engage in false or misleading promotion of Celebrex®.

47. Also included in the Warning Letter was the requirement that Pharmacia send out the "Dear Healthcare Provider" letter. Of course, the letter sent out by the manufacturer was not quite as specific as the FDA's Warning Letter. Few doctors, even if they had bothered to wade

through the difficult language, had the time or inclination to find out the story behind the letter. As a result, ***doctors continued to prescribe Celebrex® for their patients based on the allegedly scientific evidence published in JAMA***. It was incomplete and presented an inaccurate picture of the so-called safety advantage of Celebrex® over other less expensive NSAIDs.

D. Marketing and Promotion

48. Rather than financing studies to quantify the cardiovascular risks posed by Celebrex®, Defendants continued pouring money into advertising campaigns that uniformly emphasized the gastrointestinal safety of Celebrex® while avoiding any mention of cardiovascular risks. Defendants pursued this strategy to benefit from the assumption that, in the absence of information to the contrary, Celebrex® possessed the same cardioprotective properties as traditional NSAIDs.

49. Defendants' advertising expenditures quickly reached historic levels. Pharmacia and Monsanto spent more than $78 million on consumer advertising for Celebrex® in the year 2000. Defendants spent more than $400 million on direct-to consumer advertising for Celebrex® from 1999 to 2003.

50. In addition, Defendants' sales forces have blitzed doctors' offices with literature and verbal presentations designed to convince both doctors and consumers that Celebrex® was a superior drug for treatment of osteoarthritis, acute pain in adults, painful menstrual cycles and other types of disease. They have aggressively promoted Celebrex® as an improvement over other NSAIDs, like naproxen and ibuprofen, because it had a lower risk of side effects such as gastrointestinal ulcers and bleeding. Defendants did not promote or provide any balanced presentation as to Celebrex® as having an unacceptably high risk of other side effects, such as heart attack and stroke.

51. Such marketing efforts to physicians have become commonplace in recent years. Drugs, including Celebrex®, that might once have been used primarily by specialists are routinely promoted to, and prescribed by, doctors who are less familiar with the drugs' full research record.

52. Such large-scale marketing efforts have paid huge dividends to Defendants and other drug companies. The number of blockbuster drugs, defined as drugs with more than $1 billion in annual retail prescription sales, was only 15 in 1999 but grew to 34 in 2003.

53. As a result of Defendants' uniformly misleading advertising campaigns, Celebrex® was wildly successful. Celebrex® became Pharmacia's best selling drug with more than $2.6 billion in sales for 2000 and $3.1 billion in sales for 2001. After acquiring Pharmacia, Pfizer has continued to enjoy blockbuster sales of Celebrex®, with $2.3 billion in revenue through the first three quarters of 2004.

E. Risks Posed by Celebrex®

54. Despite the effectiveness of their advertising campaigns, Defendants uniform failure to disclose the risk of cardiovascular injury from Celebrex® did not quell concerns about selective COX-2 inhibitors in the medical community.

55. In 1997, the link between COX-2 inhibition, prostacyclin levels and blood clotting was receiving sporadic attention in medical journals.

56. In 1998, independent doctors established a link between selective COX-2 inhibitors and increased blood clotting, and suggested that these drugs would cause an increase in clot-related cardiovascular events. These doctors suggested that these drugs should not be given to patients with known cardiovascular disease, and that patients taking these drugs would have to be monitored for cardiovascular complications.

57. In light of the blockbuster sales of Celebrex® and the related increase in serious cardiovascular events among patients taking such drugs, the link between selective COX-2 inhibition and cardiovascular problems received increased attention.

58. The cardiovascular safety of Celebrex® was directly challenged for the first time in August 2001, when independent doctors from the Cleveland Clinic published a meta-analysis of the CLASS trial that concluded these drugs posed an increased risk of adverse cardiovascular events compared to naproxen, a traditional NSAID. These doctors, specifically concerned with the increased number of heart attacks experienced by patients taking selective COX-2 inhibitors, urged Defendants to conduct trials to assess the cardiovascular risks of Celebrex®.

59. Over the next eight months, many pre-eminent doctors and medical organizations continued to discuss the cardiovascular risk of Celebrex®. The vast majority, regardless of whether they were on Defendants' payrolls, agreed that cardiovascular risk factors should be considered in deciding whether to prescribe Celebrex®, and that well designed, comprehensive studies were needed to assess the effects of selective COX-2 inhibitors on human heart function.

60. Despite the mounting evidence that Celebrex® can cause or exacerbate clot related cardiovascular disorders, Defendants have continued to issue uniformly misleading advertisements and promotional materials that tout Celebrex® as being safe and more effective than traditional NSAIDs for all patients without regard for cardiovascular risks.

61. The FDA has issued repeated warnings identifying these marketing statements as deceptive and illegal.

62. In October 1999, the FDA sent a warning letter to Searle identifying promotional materials for Celebrex® that violated the Federal Food, Drug and Cosmetic Act because they contained unsubstantiated comparative claims of superiority with regard to other NSAIDs,

misrepresented the safety profile of Celebrex® and lacked fair balance with respect to the risks of taking Celebrex®.

63. In April 2000, the FDA sent a warning letter to Searle identifying promotional materials for Celebrex® that violated the Federal Food, Drug and Cosmetic Act because they misrepresented the safety profile of Celebrex®, contained unsubstantiated comparative claims of superiority with regard to other NSAIDs, and failed to provide any risk information concerning the use of Celebrex® promotional materials for Celebrex® that violated the Federal Food, Drug and Cosmetic Act because they suggested that Celebrex® is more effective than has been demonstrated by substantial evidence.

64. In February 2001, the FDA sent a warning letter to Pharmacia identifying promotional activities and materials for Celebrex® that violated the Federal Food, Drug and Cosmetic Act because they minimize the contraindications and risks associated with Celebrex® use and contained unsubstantiated comparative claims of superiority with regard to other NSAIDs.

65. Despite knowing the cardiovascular risks associated with Celebrex®, and having received numerous warnings from the FDA for downplaying risks associated with these drugs, Defendants sent "Dear Doctor" letters to thousands of physicians nationwide in August 2001 "strongly support[ing] the cardiovascular safety profile" of Celebrex®.

66. Despite knowing the cardiovascular risks associated with Celebrex® and having received numerous warnings from the FDA for downplaying risks associated with these drugs, Defendants also sent "Dear Patient" letters from a prescription database of thousands of consumers in August 2001 that minimized the risk of "safety issues, specifically heart attacks and strokes" associated with Celebrex® while emphasizing that these drugs were "innovative,

effective and safe" treatment options for osteoarthritis, without any mention of cardiovascular risks.

F. Misleading Promotion and Advertising

67. Defendants have spent hundreds of millions of dollars advertising Celebrex® directly to consumers. Celebrex® advertising and packaging materials do not contain any cardiovascular warnings or precautions. The only mentions of cardiovascular events are located in the "adverse reaction" (0.1%-1.9%) and "other serious adverse reaction" (<0.1%) sections, and do no more than list general cardiovascular problems experienced by participants in "12 controlled studies" involving Celebrex®.

68. Celebrex® advertising and packaging materials uniformly omit to disclose the following material facts: that there is a relationship between COX-2 inhibition and blood clotting; that Celebrex® poses a known risk of cardiovascular harm, not only to patients with heart disease and/or cardiovascular risk factors, but to all consumers; and that no clinical studies have been performed to test the safety of Celebrex® for patients with cardiovascular risk factors.

69. Defendants' advertising and packaging materials for Celebrex® are uniformly fraudulent and misleading, because they fail to warn consumers that Celebrex® poses known risks of blood clots, heart attack, stroke, unstable angina, cardiac clotting and hypertension for all people who ingest them; and cannot safely be ingested by patients with known heart disease or cardiovascular risk factors.

70. As an example, 1999 print advertisements ask: "What will you do on the day you discover Celebrex®?" The advertisements then state: "Discover what millions have turned to for arthritis pain relief." The advertisements claim that Celebrex® was a "scientific breakthrough: the first product to target only the COX-2 enzyme." They failed to explain, however, that

Celebrex® is more expensive that other NSAIDs and is no more effective than those drugs. Those advertisements also state: "Celebrex® has indigestion, diarrhea and abdominal pain. The percentage of patients who stopped taking Celebrex® due to all side effects (7.1%) was similar to sugar pill (6.1%)." The advertisements did not provide any information about potential adverse effects on consumers' hearts. Instead, at the end of a separate page in very small print, the advertisements state that the following adverse events, among others, occurred in 0.1-1.9% of patients regardless of causality: "***Cardiovascular***: Aggravated hypertension, angina pectoris, coronary artery disease, myocardial infarction." The advertisements then state, again in very small print: "Other serious adverse reactions which occur rarely (<0.1%), regardless of causality: The following serious adverse events have occurred rarely in patients, taking CELEBREX®. ***Cardiovascular***. Syncope, congestive heart failure, ventricular fibrillation, pulmonary embolism, cerebrovascular accident, peripheral gangrene, thrombophlebitis...."

71. As another example, 2001 print advertisements state: "TRUSTED SAFETY – No dose-related increase in hypertension or peripheral edema." Instead, at the end of a separate page in very small print, the advertisements state that the following adverse events, among others, occurred in 0.1-1.9% of patients regardless of causality: "***Cardiovascular***: Aggravated hypertension, angina pectoris, coronary artery disease, myocardial infarction." The advertisements then state, again in very small print: "Other serious adverse reactions which occur rarely (<0.1%), regardless of causality: The following serious adverse events have occurred rarely in patients, taking CELEBREX®. Cases reported only in the postmarketing experience are indicated in italics. ***Cardiovascular***. Syncope, congestive heart failure, ventricular fibrillation, pulmonary embolism, cerebrovascular accident, peripheral gangrene, thrombophlebitis, *vasculitis*...."

72. Defendants again failed to inform consumers of the risks of heart problems in print advertisements for the year 2003. For example, one such advertisement shows a father and son, and states: "Lasting strength. Lasting relationships." The advertisement does not reveal any risk of heart problems, although it refers to other potential risks. In very small print on a separate page, however, the advertisement sets forth the same cardiovascular risks that the 2001 advertisements set forth.

V.

STRICT PRODUCTS LIABILITY

73. Plaintiff incorporates by reference all other paragraphs of this Complaint as fully set forth herein and further alleges:

74. CELEBREX®, as designed, manufactured, sold and/or supplied by Defendants was placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition taking into consideration the utility of the product and the risks involved with the drug's use.

75. Further, CELEBREX®, as designed, manufactured, distributed, sold and/or supplied by Defendants, was defective in marketing due to inadequate warnings, instructions, and/or labeling.

76. CELEBREX®, as designed, manufactured, distributed, marketed, sold and/or supplied was defective due to inadequate testing.

77. Plaintiff alleges CELEBREX® was defective in design and/or formulation in that, when it left the hands of Defendants and/or their representatives, agents or assignees, the foreseeable risks of serious harm posed by this drug far exceeded its alleged benefits. The foreseeable risks of serious harm were such that Plaintiff and the general public, having known

of such foreseeable risks and alleged benefits, would not have ingested CELEBREX®.

78. CELEBREX® was also defective due to inadequate warnings and misrepresentations to healthcare professionals. Defendants knew that had healthcare professionals been adequately warned of the serious risks of injury to their patients, healthcare professionals would not have prescribed CELEBREX® to patients.

79. CELEBREX® was defective due to inadequate testing both before and after Defendants became aware of the risks of ingesting the drug.

80. As the producing and direct cause and legal result of the design defect and/or the marketing defect due to the Defendants' failure to warn consumers, as well as the defective condition of the drug as manufactured and supplied by Defendants and their representatives, Plaintiff David R. Dunn suffered injuries and monetary damages.

VI.

FRAUD

81. Plaintiff incorporates by reference all other paragraphs of this Complaint as fully set forth herein and further alleges:

82. Defendants fraudulently represented to the general public, as well as healthcare professionals, that CELEBREX® was a safe and effective drug. Defendants made this representation while knowing that, if healthcare professionals and consumers knew of the serious risks associated with the ingestion of the CELEBREX® drug, they would not prescribe and/or ingest this drug. Defendants knew their representations to be false, and Plaintiff David R. Dunn relied on Defendants' false representations in Plaintiff's ingestion of CELEBREX®. These fraudulent representations by Defendants were a proximate cause of the injuries to and monetary losses of Plaintiff.

VII.

NEGLIGENCE

83. Plaintiff incorporates by reference all other paragraphs of this Complaint as fully set forth herein and further alleges:

84. Defendants and their representatives were merchants or sellers of CELEBREX®. Defendants had a duty to exercise reasonable care in the design, manufacturing, marketing, sale, testing and/or distribution of this drug into the stream of commerce. Defendants failed to exercise ordinary care in the design, manufacturing, marketing, sale, testing, and/or distribution of the CELEBREX® drug into interstate commerce. Defendants knew, or should have known, that their CELEBREX® drug greatly increased Plaintiff's risks of having a heart attack and/or stroke, or worse, of causing Plaintiff's death.

85. Despite the fact that Defendants knew, or should have known that CELEBREX® could cause unreasonable injurious results and/or death to Plaintiff, these Defendants continued to market, distribute, and sell CELEBREX® to the public.

86. Defendants knew, or should have known that consumers, such as Plaintiff would foreseeably suffer injuries and/or death as a result of Defendant's failure to exercise ordinary care as described above. Moreover, after Defendants became aware of the serious risks of ingesting CELEBREX®, they owed a legal duty to Plaintiff, and the general public, to disclose that knowledge. Defendant's breach of their duty to disclose this information was a proximate cause of the injuries to Plaintiff.

VIII.

NEGLIGENT MISREPRESENTATIONS

87. Plaintiff incorporates by reference all other paragraphs of this Complaint as fully set

forth herein.

88. Defendants represented and marketed the CELEBREX® drug as being safe and effective. After Defendants became aware of the risk of ingesting CELEBREX®, however, Defendants failed to communicate to Plaintiff and/or the general public, that the ingestion of this drug could cause a person to suffer a heart attack or stroke, or that the CELEBREX® drug could cause the death of the person ingesting the drug.

89. Therefore, Plaintiff brings this cause of action against Defendants under the theory of negligent misrepresentation for the following reasons:

a) Plaintiff incorporates all facts and allegations previously stated in this Complaint;

b) Defendants failed to warn Plaintiff, and other consumers, of the defective condition of the CELEBREX® as manufactured and/or supplied by Defendant Pfizer;

c) Defendants, individually, and through their agents, representatives, distributors, and/or employees, negligently misrepresented material facts about CELEBREX® in that they made such misrepresentations when they knew or reasonably should have known of the falsity of such misrepresentations. Alternatively, Defendants made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations.

d) The above misrepresentations were made to Plaintiff, as well as the general public;

e) Plaintiff David R. Dunn and Plaintiff's healthcare provider justifiably relied on Defendant's misrepresentations; and

f) Consequently, Plaintiff's ingestion of CELEBREX® was to the Plaintiff's detriment. Defendants' negligent misrepresentations proximately caused Plaintiff's injuries and monetary losses.

IX.

EXPRESSED WARRANTY FOR GOODS

90. Plaintiff incorporates by reference all other paragraphs of this Complaint as fully set forth herein and further alleges:

91. Defendants breached their express warranty of goods. Defendants were merchants and/or sellers of the CELEBREX® drug. Defendants sold this drug to consumers for the ordinary purpose for which such drugs are used by consumers. Defendants owed a legal duty to Plaintiff and the public in general, to disclose their knowledge of the serious risks of ingesting the CELEBREX® drug as marketed. This breach of duty by Defendants was a proximate cause of the injuries and monetary loss to Plaintiff.

X.

IMPLIED WARRANTY

A. WARRANTY OF MERCHANT ABILITY.

92. Plaintiff incorporates by reference all other paragraphs of this Complaint as fully set forth herein and further allege:

93. Defendants breached their implied warranty of merchantability. Defendants were merchants and/or sellers of the CELEBREX® drug. Defendants sold this drug to Plaintiff, and other consumers, for the ordinary purpose for which such drug is used by consumers. CELEBREX® was defective, or unmerchantable, i.e., not fit for the ordinary purposes for which such drugs are used. A defect or defects in the use of this drug for its ordinary purposes caused injuries and monetary losses to Plaintiff.

B. WARRANTY OF FITNESS

94. Plaintiff incorporates by reference all other paragraphs of this Complaint as fully set

forth herein, and further allege:

95. Defendants breached their implied warranty of fitness. Defendants sold the CELEBREX® drug, and, at the time of the sale of this drug, Defendants knew or had reason to know of a particular purpose for which the drug was to be used. At the time of the sale of the drug to Plaintiff, Defendants knew, or had reason to know, that Plaintiff was relying on the skill and judgment of Defendants to select or furnish a suitable product for the intended purpose. At the time of the sale of the drug to Plaintiff, Defendants exercised their skill and judgment in the selection of this drug as safe and effective, and Plaintiff relied thereon. The CELEBREX® drug was not reasonably fit and/or suitable for the use for which it was selected. Failure of Defendants to select and sell a product which was reasonably safe for its intended use proximately caused the injuries and monetary losses to Plaintiff.

XI.

DAMAGES

96. Upon the trial of this case, it will be shown that Plaintiff was caused to sustain serious injuries and damages as a proximate result of Defendants' conduct. Plaintiff will respectfully request the Court and Jury to determine the amount of the loss Plaintiff has incurred in the past and will incur in the future, not only from a financial standpoint, but also in terms of good health and freedom from pain and worry.

XII.

PUNITIVE DAMAGES

97. At all times relevant hereto, Defendants actually knew of the defective nature of the CELEBREX® drug as set forth herein and continued to design, manufacture, market, distribute and sell the CELEBREX® drug so as to maximize sales and profits at the expense of the public's

health and safety and in conscious disregard of the foreseeable serious harm caused by the CELEBREX® drug. Defendants' conduct exhibits such an entire want of care as to establish that their actions were a result of fraud, ill will, recklessness, and/or willful and intentional disregard for the safety and rights of Plaintiff, as well as the general public and/or consumers of the CELEBREX® drug. Plaintiff, therefore, is entitled to punitive damages for such conduct.

XIII.

JURY DEMAND

98. Plaintiff hereby requests a trial by jury on all issues in this case.

XIV.

PRAYER

WPLAINTIFF'SEFORE, PREMISES CONSIDERED, Plaintiff prays that upon trial hereof, the Court grant:

1. Judgment against Defendants for actual damages, as set forth above, in an amount in excess of the minimum jurisdictional limits of this Honorable Court;

2. Interest on said Judgment, at the legal rate from the date of the Judgment;

3. Plaintiff's costs of this suit;

4. Past and future, physical and mental, pain, suffering, anguish and disabilities of Plaintiff;

5. Past medical expenses of Plaintiff;

6. Future medical expenses of Plaintiff;

7. Prejudgment interest as allowed by law;

8. Any additional damages and punitive damages under the facts set forth in this or any amended pleading(s); and

9. For such other and further relief to which Plaintiff may prove to be justly entitled, both in law and in equity.

Respectfully submitted,

ANDRUS BOUDREAUX, PLC

BY: _____

VANCE R. ANDRUS, ESQ.
Colorado State Bar No. 30764

ANDRUS BOUDREAUX, PLC
1775 Sherman St., Suite 3100
Denver, CO 80203
PHONE: (303) 376-6360
FAX: (303) 376-6361
and
416 W. Main Street
Lafayette, LA 70501

ATTORNEY IN CHARGE FOR PLAINTIFF

Richard J. Arsenault, Esq.
C. Michael Bollinger, Esq.
Neblett, Beard & Arsenault
2220 Bonaventure Court
Alexandria, LA 71301
(318) 487-9874 Phone
(318) 561-2591 Facsimile

Bryan F. Aylstock, Esq.
Justin G. Witkin, Esq.
Neil D. Overholtz, Esq.
Douglass A. Kreis, Esq.
Aylstock, Witkin & Sasser, PLC
4400 Bayou Boulevard, Suite 58
Pensacola, FL 32503-1909
(850) 916-7450 Phone
(850) 916-7449 Facsimile

Dawn M. Barrios, Esq.
Bruce Kingsdorf, Esq.
Barrios, Kingsdorf & Casteix, L.L.P.
One Shell Square
701 Poydras Street, Suite 3650
New Orleans, LA 70139-3650

Matthew E. Lundy, Esq.
Lundy & Davis, L.L.P.
333 North Sam Houston Pkwy. E, Suite 375
Houston, TX 77060-2487
(281) 272-0797 Phone
(281) 272-0781 Facsimile

CO-COUNSEL FOR PLAINTIFF